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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/724,868

11/28/2000

Xanthe M. Lam

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06/03/2004

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,868

Applicant(s)

LAM ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/00, 8/11/03 and 2/11/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-42 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/15/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendments filed 11/28/00 and 8/11/03 and Applicant's response filed 2/11/04 are acknowledged and have been entered.
2. Applicant's election without traverse of Group I (claims 24-43), and species of antibody/fragment thereof of F(ab')₂ at about 0.1 to about 50 mg/ml, the polyol trehalose nonreducing sugar, acetate buffer in an amount of about 5-30 mM, polysorbate surfactant in an amount of about 0.01 %-0.1 % v/v, benzyl alcohol preservative at about 0.1 % to about 2 % in Applicant's response filed 2/11/04 is acknowledged.

Claims 24-31, 33-35, 37, 38, 40, 41 and 42 read on the elected species.

Upon consideration of the prior art, the search has been extended to include the species recited in claims 32, 36, 39 and 43.

Accordingly, claim 44 (non-elected Group II) is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 24-43 are currently being examined.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: there is no citizenship set forth for inventor Shahrokh.

4. The disclosure is objected to because of the following informalities:

- a. A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because the top margin spacing does not appear to be correct, i.e., is not large enough. The first line of text on each page is partially occluded by holes punched for file placement.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and (c).

- b. In light of Applicant's amendment to the specification filed 11/28/00, i.e., the direction to amend the specification by inserting a sentence before line 1 on page 1 of the specification. Applicant is required to delete the sentence between "Related Application" and "Field of the

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Invention" on page 1 because it is a duplicate of the priority information with regard to provisional application 60/053,087 inserted by the amendment of 11/28/00.

c. There should be a space in between "herein" and "below" on page 6 of the specification at line 26.

Appropriate corrections are required.

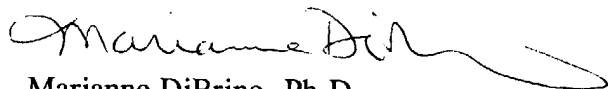
5. Claim 43 is objected to because of the following informality. It appears that the limitation "polysorbate" at line 2 should be "a polysorbate". Appropriate correction is required.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




Marianne DiBrino, Ph.D.

Patent Examiner

Group 1640

Technology Center 1600

May 24, 2004



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600